### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

LEUNG et al.

Docket No.:

39766-0128A

Serial No.:

09/422,528

Group Art Unit: 1652

Filing Date:

October 21, 1999

Examiner:

Fronda, Christian L.

For:

AUG 2 4 2005

PROCESS FOR BACTERIAL PRODUCTION OF

**POLYPEPTIDES** 

## **DECLARATION OF WOON-LAM S. LEUNG**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### Dear Sir:

- I, WOON-LAM S. LEUNG, do declare and say as follows:
- 1. I am an inventor of the above-identified patent application.
- I am familiar with claims 1-25 under examination in the above-identified 2. patent application.
- 3. I am a co-author of Leung et al., Book of Abstracts, 216th ACS National Meeting, Boston, August 23-27 (1998) BIOT-014 ("Leung et al. Abstract"), along with John C. Joly and James R. Swartz.
- It is my belief, based upon my personal knowledge of the individual 4. contributions of each of the co-authors inventors of the Leung et al. Abstract, and my understanding of the subject matter of claims 1-25 of the present application that the work relating to the recovery of reflactile particles (RPs) containing a heterologous polypeptide, such as IGF-I, from bacterial periplasm in which the polypeptide is insoluble, is the joint invention of James R. Swartz and myself, and John C. Joly made no inventive contribution.

5. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further, that these statements are made with the knowledge that willful statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent granted thereon.

Dated: 6/4/05

WOON-LAM S. LEUNG

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# **DECLARATION OF JAMES R. SWARTZ**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### Dear Sir:

I, JAMES R. SWARTZ, do declare and say as follows:

- 1. I am an inventor of the above-identified patent application.
- 2. I am familiar with claims 1-25 under examination in the above-identified patent application.
- 3. I am a co-author of Leung et al., Book of Abstracts, 216th ACS National Meeting, Boston, August 23-27 (1998) BIOT-014 ("Leung et al. Abstract"), along with John C. Joly and James R. Swartz.
- 4. It is my belief, based upon my personal knowledge of the individual contributions of each of the co-authors inventors of the Leung et al. Abstract, and my understanding of the subject matter of claims 1-25 of the present application that the work relating to the recovery of reflactile particles (RPs) containing a heterologous polypeptide, such as IGF-I, from bacterial periplasm in which the polypeptide is insoluble, is the joint invention of Woon-Lam S. Leung and myself, and John C. Joly made no inventive contribution.

5. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further, that these statements are made with the knowledge that willful statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent granted thereon.

Dated: June 2, 2005

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